Appl. No.: 10/706,243

Art Unit: 1616

Reply to Office Action of 09/16/2009

Patent 1951300.00066

## **Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

## **Listing of Claims:**

1-22. (Canceled)

- 23. (Previously Presented) A method for delivery of an active agent to the pulmonary system comprising: administering to a patient in need of treatment an effective amount of a dry powder comprising microparticles which comprise a diketopiperazine and the active agent and which have a diameter between 0.5 microns and ten microns, in a pharmaceutically acceptable carrier for administration to the lungs, wherein the carrier is air, wherein the microparticles are administered from a dry powder inhaler or from a container for a dry powder inhaler; and wherein the active agent is released from the microparticle at a pH of 6.0 or greater.
- 24. (Currently Amended) The method of claim 23, wherein the diketopiperazine has the formula 2, 5 -diketo-3,6-di(4-X-aminobutyl)piperazine, wherein X is selected from the group consisting of succinyl, glutaryl, maleyl, and furmarylfumaryl.
  - 25. (Previously Presented) The method of claim 24, wherein X is fumaryl.
- 26. (Previously Presented) The method of claim 23, wherein the agent is a therapeutic agent selected from the group consisting of insulin, calcitonin, felbamate, heparin, parathyroid hormone and fragments thereof, growth hormone, erythropoietin, zidovudine (AZT), didanosine (DDI), granulocyte colony stimulating factor (G-CSF), iamotrigine, chorionic gonadotropin releasing factor, luteinizing releasing harmone,  $\beta$ -galactosidase, and Argatroban.
  - 27 39. (Canceled)
- 40. (Previously Presented) A microparticulate system for drug delivery to the pulmonary system comprising: a dry powder comprising microparticles having a size

Appl. No.: 10/706,243

Art Unit: 1616

Reply to Office Action of 09/16/2009

Patent 1951300.00066

range of between 0.5 and ten microns, wherein the microparticles comprise an effective amount of a drug to be delivered and a diketopiperazine, and wherein the microparticles release the drug at a pH of 6.0 or greater, in a pharmaceutically acceptable carrier for administration to the lungs, wherein the carrier is air, and wherein the microparticles are in a dry powder inhaler or a container for a dry powder inhaler.

- 41. (Previously Presented) The system of claim 40, consisting essentially of the drug and the diketopiperazine.
- 42. (Previously Presented) The system of claim 40, wherein the diketopiperazine has the formula 2, 5 -diketo-3,6-di(4-X-aminobutyl)piperazine wherein X is selected from the group consisting of succinyl, glutaryl, maleyl, and fumaryl.
  - 43. (Previously Presented) The system of claim 42, wherein X is fumaryl.
- 44. (Previously Presented) The system of claim 40, wherein the drug is selected from the group consisting of insulin, calcitonin, felbamate, heparin, parathyroid hormone and fragments thereof, growth hormone, erythropoietin, zidovudine (AZT), didanosine (DDI), granulocyte colony stimulating factor (C-CSF), lamatrigine, chorionic gonadotropin releasing factor, luteinizing releasing hormone,  $\beta$ -galactosidase, and Argatroban.
- 45. (Previously Presented) The system of claim 44, wherein the drug is insulin.
- 46. (Previously Presented) The method of claim 26, wherein the drug is insulin.
- 47. (Previously Presented) A cartridge for insertion into an inhaler comprising dry microparticles having a size range of between 0.5 and ten microns comprising a drug to be delivered by inhalation, wherein the microparticles comprise a diketopiperazine and the drug, and wherein the microparticles release the drug at a pH of 6.0 or greater.
- 48. (Previously Presented) The cartridge of claim 47, wherein the drug is selected from the group consisting of insulin, calcitonin, felbamate, heparin, parathyroid

Appl. No.: 10/706,243

Art Unit: 1616

Reply to Office Action of 09/16/2009

Patent 1951300.00066

hormone and fragments thereof, growth hormone, erythropoietin, zidovudine (AZT), didanosine (DDI), granulocyte colony stimulating factor (G-CSF), lamotrigine, chorionic gonadotropin releasing factor, luteinizing releasing hormone, β-galactosidase, and Argatroban.

49. (Previously Presented) The cartridge of claim 48, wherein the drug is insulin.

50 - 54. (Canceled)

- 55. (New) The method of claim 47, wherein the diketopiperazine has the formula 2, 5 -diketo-3,6-di(4-X-aminobutyl)piperazine, wherein X is selected from the group consisting of succinyl, glutaryl, maleyl, and fumaryl.
  - 56. (New) The method of claim 47, wherein X is fumaryl.